Complete Summary

GUIDELINE TITLE

Rituximab for aggressive non-Hodgkin´s lymphoma.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Rituximab for aggressive non-Hodgkin's lymphoma. London (UK): National Institute for Clinical Excellence (NICE); 2003 Sep. 22 p. (Technology appraisal; no. 65).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 18, 2006 - Rituxan (Rituximab): Health care professionals informed about important emerging safety information regarding the development of progressive multifocal leukoencephalopathy (PML) in patients under treatment with Rituxan.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Aggressive non-Hodgkin's lymphoma (i.e., CD20-positive diffuse large B-cell lymphoma)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Radiation Oncology

INTENDED USERS

Advanced Practice Nurses
Health Plans
Managed Care Organizations
Physician Assistants
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

- To assess the clinical and cost-effectiveness of adding rituximab to cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) for adult patients (18 or over) with diffuse large-B-cell lymphoma
- To assist the National Health Service (NHS) in England and Wales determine when rituximab should be used

TARGET POPULATION

Adult patients (18 or over) with aggressive non-Hodgkin's lymphoma (i.e., CD20-positive diffuse large-B-cell lymphoma at clinical Stage II, III, or IV)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP)
2. Cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) alone

MAJOR OUTCOMES CONSIDERED

Clinical Effectiveness

The primary outcome was survival free of progression, relapse or death. Secondary outcomes were overall survival, response rates, and toxic effects.

Cost Effectiveness

Costs/Quality Adjusted Life Years (QALY)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the University of Sheffield, School of Health and Related Research (see the "Companion Documents" field).

Data Sources

Fifteen electronic bibliographic databases were searched to identify all literature relating to the clinical and cost effectiveness of rituximab for the treatment of aggressive non-Hodgkin's lymphoma.

Clinical Effectiveness

This systematic review was carried out according to the recommendations of the QUOROM statement (Appendix 4 of the Assessment Report [see the "Availability of Companion Documents" field]).

Search Strategy

The search aimed to identify all literature relating to the clinical and cost effectiveness of rituximab (MabThera®) for the treatment of aggressive non-Hodgkin's lymphoma. The main searches were conducted in August and September 2002.

Sources Searched

Fifteen electronic bibliographic databases were searched, covering biomedical, science, social science, health economic and grey literature.

In addition, the reference lists of relevant articles and sponsor submissions were hand searched and various health services research related resources were consulted via the Internet. These included health economics and health technology assessment organisations, guideline producing agencies, generic research and trials registers, and specialist sites. A list of additional sources is given in Appendix 6 of the Assessment Report (see the "Availability of Companion Documents" field). Citation searches were conducted on the key paper and its author using the Science and Social Science Citation Index facilities, Medline and Embase.

Search Terms

A combination of free-text and thesaurus terms were used. 'Population' search terms (e.g., lymphoma, lymphocytes, non-Hodgkin's, high-grade, intermediate-grade, large cell) were combined with 'intervention' terms (e.g., Rituximab, MabThera, Rituxan, antineoplastic agents, etc.).

Search Restrictions

No language, study/publication, or date restrictions were applied to the main searches. The main searches performed in Medline and Embase included filters for systematic reviews/meta-analyses, economic/QoL evaluations, controlled trials, and guidelines, in order to assist with the identification of these types of articles (all other study types were also saved).

Inclusion and Exclusion Criteria

The structured title was formulated as, 'rituximab plus CHOP versus CHOP alone for DLBCL.' Comparative studies were included if: (a) the study population had untreated diffuse large-B-cell lymphoma (DLBCL) that had been diagnosed according to the Revised European American Lymphoma (REAL), or REAL-World Health Organization (WHO) classificatory schema; (b) the study intervention was rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP), and the study comparator was CHOP alone (where the cycles of CHOP in each arm were identical); and, (c) study endpoints included event-free survival (see below for definition). There were no language restrictions and studies reported only in abstract form were reported.

Reasons for exclusion were: (a) a non-comparative study design; (b) populations other than those described above; (c) absence of the interventions and/or comparators described above; and, (d) absence of 'event-free survival as the primary outcome of interest'.

The abstracts of potentially relevant citations were reviewed. After examining the full manuscripts of all potentially relevant abstracts, those deemed to be potential randomised controlled trials relating directly to the structured title were obtained.

Cost Effectiveness

One economic evaluation of rituximab in combination with CHOP (R-CHOP) versus CHOP was supplied by the manufacturer. Costs were estimated through resource

use data taken from the published trial and the unpublished sponsor submission. Unit costs were taken from published sources, where available.

Refer to the "Cost Analysis" field for more information.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

The search retrieved 5,273 citations. One study was included.

Cost Effectiveness

One economic evaluation of rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) versus cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) was supplied by the manufacturer.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the University of Sheffield, School of Health and Related Research (ScHARR) (see the "Companion Documents" field).

Clinical Effectiveness

Data Extraction Strategy

Data extraction was completed independently by two researchers and disagreement resolved by consensus. The Scottish Intercollegiate Guidelines Network (SIGN) forms were used for data extraction. Data on event-free survival, response rate, survival and safety were abstracted as reported.

Quality Assessment Strategy

The Jadad checklist was used to determine study quality of randomised controlled trials. Two reviewers independently undertook the quality assessment with any differences resolved by consensus.

Cost Effectiveness

The economic model developed by ScHARR uses the framework of the Hoffman La Roche (ROCHE) model, but it has incorporated different modelling assumptions. The main differences are:

- The interpretation of the number of life years gained attributed to treatment with cyclophosphamide, vincristine, prednisolone and doxorubicin (CHOP) from survival curves of patients with acute large B-cell non-Hodgkin's lymphoma.
- The interpretation of the increase in life years gained attributed to the inclusion of rituximab to the CHOP treatment.
- The inclusion of other treatment costs attributed to patients who fail to respond to CHOP and/or Rituximab treatment.

The model evaluates the cost-effectiveness of introducing rituximab to the treatment regimen of CHOP (R-CHOP) compared to a CHOP only treatment regimen.

The model is a Markov transition model with 3 health states that split into two age cohorts, those aged 60 and over and those aged less than 60 years old. The 3 states are complete responder (CR) to treatment, non-responder and relapse from complete responders (NR) to treatment, and death. The proportion of patients that achieved a complete response upon receiving CHOP for DLBCL and the duration of overall survival of patients who have received a CHOP regimen has been derived from the Scottish and Newcastle lymphoma group (SNLG) database acquired by ROCHE and kindly provided to ScHARR. The observed survival data from the SNGL database has been uses to reflect the transitions between the health states over time. The relative effectiveness of R-CHOP compared to a CHOP only treatment regimen for patients with diffuse-large B-cell lymphoma (DLBCL) has been derived from the published literature based on the Group d'Etude des Lymphomes de l'Adulte (*GELA*) studies. The model calculates an incremental cost-effectiveness ratio over a 15-year time horizon. The cost-effectiveness ratio is the additional cost of Rituximab with CHOP chemotherapy (R-CHOP) per the additional benefits of R-CHOP therapy. The additional benefits gained are measured as quality adjusted life years (QALY).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the University of Sheffield, School of Health and Related Research (ScHARR) (see the "Companion Documents" field).

Cost Effectiveness

One economic evaluation of rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) versus cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) was supplied by the manufacturer. However, the Assessment Group incorporated a number of different assumptions into the framework of the manufacturer's model as part of the review process.

Both versions of the model included only the costs to the NHS, expressed health benefits in terms of quality-adjusted life-years (QALYs), and used a 15-year time horizon. Both versions of the model also estimated utilities from the same unpublished study. The estimates of the proportion of people achieving complete response and the overall duration of survival in people receiving the CHOP regimen were based on observational data. The estimate of the relative treatment effect for R-CHOP was based on the single randomised controlled trial. Both versions of the model also used these data to estimate cost effectiveness separately for people younger than 60 years of age.

The manufacturer's version of the model produced a cost per life-year gained of approximately £4500 and a cost per quality-adjusted life-year gained (QALY) of £6100 for people aged 60 years and older. For people younger than 60 years, these figures were approximately £4700 and £6800 respectively. Sensitivity analysis showed that these incremental cost-effectiveness ratios (ICERs) were relatively robust to changes in the input assumptions. However, the ICERs approximately doubled when the time horizon was reduced to 5 years.

The Assessment Group's version of the model differed from the manufacturer's mainly in the interpretation of the survival curves for people receiving CHOP or R-CHOP and the inclusion of other costs associated with treatment failure (second-line therapies and palliative care costs). The results for people younger than 60 years were slightly less favourable than those from the manufacturer: approximately £8500 per life-year gained and £7500 per QALY gained. In people aged 60 years and older, the ICERs were less favourable: about £9700 per life-year gained and £10,500 per QALY gained. Extensive sensitivity analyses found these results to be robust to changes in the input assumptions. Probabilistic sensitivity analysis estimated that there was only a 5% chance that the cost per additional QALY would exceed £23,400 in people aged 60 years and older, or £19,000 in people younger than 60 years.

Both versions of the model suggest that rituximab in combination with each of eight cycles of CHOP is cost effective relative to CHOP used alone.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Rituximab is recommended for use in combination with a regimen of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) for the first-line treatment of people with CD20-positive diffuse large-B-cell lymphoma at clinical stage II, III or IV (see Section 2.3 of the original guideline document). Rituximab is not recommended for use when CHOP is contraindicated.
- The clinical and cost effectiveness of rituximab in patients with localised disease (Stage I, see Section 2.3 of the original guideline document) has not been established. It is recommended that rituximab be used in these circumstances only as part of ongoing or new clinical studies.
- A specialist in the treatment of lymphomas should supervise the use of rituximab in combination with CHOP for the treatment of diffuse large-B-cell lymphoma.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations for clinical effectiveness are based on one randomised controlled trial.

For cost effectiveness, the Assessment Group developed its own economic model and considered an economic evaluation supplied by the manufacturer.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Clinical Effectiveness

In the systematic review of effectiveness, one randomised trial was identified. In the short-term, the addition of rituximab to the cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) regimen significantly increased the likelihood of a complete-response, without a significant rise in the risk of a serious adverse event, in people aged 60 or over. Over a two-year follow-up period, the intervention significantly prolonged survival without progression or relapse (the primary outcome), and significantly prolonged overall survival in this population. There is no direct evidence for the clinical effectiveness of adding rituximab to CHOP in the treatment of diffuse large-B-cell lymphoma in those aged 18 to 59 years, although data from phase I and II trials confirm its safety and efficacy in a pre-clinical setting. Arguments are presented that clinical effectiveness can be derived for a younger population on the grounds that disease biology is consistent by age and prognosis is inversely correlated with age.

Cost-Effectiveness

The cost-effective modelling presented in the Assessment Report (see "Availability of Companion Documents" field) has shown that rituximab when used in combination with CHOP chemotherapy regimen is a cost-effective treatment for diffuse large B-cell lymphoma when compared to the current standard treatment with CHOP chemotherapy only. Although both the University of Sheffield, School of Health and Related Research (ScHARR) model and the Hoffmann La Roche (ROCHE) model are based on the same data and use the same methodology, different interpretations of the clinical outcomes and costs has resulted in different results. However, the difference in the cost/quality-adjusted life-year (QALY) answers does not lead to a difference in the overall result that the addition of rituximab to the CHOP regimen is a cost-effective treatment. Extensive sensitivity analysis undertaken in both models has shown the results to be particularly robust.

POTENTIAL HARMS

Adverse events associated with rituximab include infusion-related reactions, which occur in more than 50% of people. These are predominantly seen during the first infusion, usually during the first 1-2 hours, and include fever, chills and rigors. Other adverse events include flushing, angioedema, nausea, urticaria/rash, fatigue, headache, throat irritation, rhinitis, vomiting and tumour pain. In about 10% of people these adverse events are accompanied by hypotension and bronchospasm. There have been post-marketing reports of more serious infusion-related reactions in a very small proportion of people. Fatal outcomes have been reported for people who developed features of cytokine-release syndrome and/or signs and symptoms of tumour-lysis syndrome.

For full details of side effects, precautions and contraindications, see the Summary of Product Characteristics, available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

Rituximab is contraindicated in patients with known hypersensitivity to any of its components or to murine proteins.

For full details of side effects, precautions and contraindications, see the Summary of Product Characteristics, available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgment. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- Clinicians with responsibility for treating people with CD20-positive diffuse large-B-cell lymphoma (DLBCL) should review their current practice and policies to take account of the guidance set out in Section 1 of the original guideline document (see the "Major Recommendations" field).
- Local guidelines, protocols or care pathways that refer to the care of people with CD20-positive DLBCL should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - An individual with CD20-positive DLBCL at clinical stage II, III or IV is provided with rituximab in combination with a regimen of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) for first-line treatment, unless this treatment is contraindicated.
    - An individual with DLBCL that is localised (stage I or IE) is provided with rituximab only as part of ongoing or new clinical studies.
    - A specialist in the treatment of lymphomas supervises the use of rituximab in combination with CHOP to treat DLBCL.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Rituximab for aggressive non-Hodgkin's lymphoma. London (UK): National Institute for Clinical Excellence (NICE); 2003 Sep. 22 p. (Technology appraisal; no. 65).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Sep

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Rituximab for aggressive non-Hodgkin's lymphoma. Summary. London (UK): National Institute for Health and Clinical Excellence (NICE); 2003 Sep. 2 p. (Technology appraisal 65). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Rituximab (MabThera) for aggressive non Hodgkin's lymphoma: systematic review. Assessment report. NHS R&D HTA Programme. 81 p. Available in

Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0285. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Rituximab for aggressive non-Hodgkin's lymphoma. Understanding NICE guidance--information for people with non-Hodgkin's lymphoma, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2003 Sep. 10 p. (Technology appraisal 65).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0286. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 18, 2006. This summary was updated by ECRI on January 12, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rituxan (Rituximab).

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Date Modified: 9/29/2008